Citation:

Ventura E, Davis J, Byrd-Williams C, Alexander K, McClain A, Lane CJ, Spruijt-Metz D, Weigensberg M, Goran M. Reduction in risk factors for type 2 diabetes mellitus in response to a low-sugar, high-fiber dietary intervention in overweight Latino adolescents. *Arch Pediatr Adolesc Med.* 2009 Apr;163(4):320-7.

PubMed ID: 19349560

Study Design:

Randomized controlled trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To examine if reductions in added sugar intake or increases in fiber intake in response to a 16-week intervention were related to improvements in metabolic outcomes related to type 2 diabetes mellitus risk.

Inclusion Criteria:

- BMI in the 85th percentile or higher
- Latino ethnicity
- Grades 9 through 12

Exclusion Criteria:

- Using medication or were diagnosed with any syndrome or disease that could influence dietary intake, exercise ability, body composition and fat distribution, or insulin action and secretion
- Were previously diagnosed with any major illness
- Met diagnostic criteria for diabetes
- Participated in a structured exercise, nutrition or weight loss program in the past 6 months

Description of Study Protocol:

Recruitment

Participants were recruited from Los Angeles County. Recruitment methods not described.

Design: Cohort study; secondary analysis of combined randomized controlled trial data

Blinding used (if applicable): implied with measurements

Intervention (if applicable)

Intervention classes at a lifestyle laboratory and metabolic measures at the General Clinical Research Center. 16 week study with 3 groups:

- Control group received no intervention
- Nutrition group received 1 nutrition class per week for 16 weeks, which targeted a decrease in added sugar consumption and an increase in fiber consumption
- Nutrition plus strength training group received the same weekly nutrition classes along with strength training 2 times per week for 16 weeks

Statistical Analysis

- Subjects were divided into categories based on whether they decreased sugar intake and/or increased fiber intake
- Baseline characteristics were compared between sugar and fiber intake change categories using chi-squared tests and independent t tests
- Since there were no significant differences in sugar or fiber intake change by randomization group, all participants were combined for subsequent analyses
- Preliminary analysis of raw change scores for metabolic outcomes were tested for significance against zero with independent t tests
- Repeated measures ANCOVA was conducted

Data Collection Summary:

Timing of Measurements

At both baseline and 16 weeks, participants had both an outpatient and inpatient clinic visit for assessment of insulin and glucose indexes, anthropomorphics, body composition and dietary intake.

Dependent Variables

- Weight and height measured, BMI calculated
- Body composition by dual energy x-ray absorptiometry
- Visceral adipose tissue by magnetic resonance imaging
- Glucose and insulin incremental area under the curve by oral glucose tolerance test
- Insulin sensitivity
- Acute insulin response
- Disposition index by intravenous glucose tolerance test

Independent Variables

- Control group received no intervention
- Nutrition group received 1 nutrition class per week for 16 weeks, which targeted a decrease in added sugar consumption and an increase in fiber consumption
- Nutrition plus strength training group received the same weekly nutrition classes along with strength training 2 times per week for 16 weeks
- Dietary intake measured with 3-day food records

Control Variables

- Sex
- Randomization group
- Baseline sugar and/or fiber intake

Description of Actual Data Sample:

Initial N: 66 participants were randomized

Attrition (final N): 54 adolescents completed the trial. 49 had available dietary data, DEXA measured in 45 subjects, and MRI measured in 40 subjects.

Age: mean age 15.5 ± 1 years

Ethnicity: Latino

Other relevant demographics:

Anthropometrics

There were no statistically significant differences in baseline demographics, anthropometrics, or boyd composition measures between the 12 partipants who dropped out and the 54 completers.

Location: California

Summary of Results:

Key Findings

- 55% of all participants decreased added sugar intake (mean decrease of 47 ± 42 g/day) and 59% increased fiber intake (mean increase of 5 ± 8 g/day) and percentages were similar in all intervention groups, including controls
- There was a trend toward significance for the sugar intake decreasers to have a higher BMI at baseline than the sugar intake increasers (35.6 vs 32.0, P = 0.08).
- Those who decreased added sugar intake had an improvement in glucose incremental area under the curve (-15% vs +3%, P = 0.049) and insulin incremental area under the curve (-33% vs -9%, P = 0.02).
- Those who increased fiber intake had an improvement in body mass index (-2% vs +2%, P = 0.01) and visceral adipose tissue (-10% vs no change, P = 0.03).
- There was considerable overlap in sugar and fiber intake categories: 78% (21 of 27) of those who reduced sugar intake also increased fiber intake, and 72% (21 of 29) of those who increased fiber intake also decreased sugar intake.
- However, when sugar and fiber intake categories were tested together in the same model, there were no significant interactions for any of the adiposity measures or glucose/insulin indexes.

Author Conclusion:

In conclusion, through this secondary analysis of response to a 16-week intervention, we found that overweight Latino youth who decreased added sugar intake or increased fiber intake showed

stronger improvements in risk factors for type 2 diabetes, specifically in insulin response to an oral glucose challenge or in visceral fat. Modest changes in sugar and fiber consumption, equivalent to omitting 1 can of soda or adding 1 serving of beans daily, could lead to substantial improvements in adiposity and metabolic parameters. Furthermore, given that the control group demonstrated similar dietary changes as the intervention groups, our results suggest that intensive interventions may not be necessary to achieve modifications in sugar and fiber intake. Accordingly, nutritional guidance given in the primary care or community setting may be sufficient to promote the suggested dietary changes in some individuals. In addition, policies that promote reduced intake of added sugar and increased intake of fiber could be effective public health strategies for the prevention of type 2 diabetes in this high-risk population.

Reviewer Comments:

Recruitment methods not described. Measurements not made in all subjects.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes

2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	No
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	???
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A

5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	Yes
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	Yes
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	???
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes

8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**		Yes
	8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
	8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
	8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
	8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
	8.6.	Was clinical significance as well as statistical significance reported?	Yes
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		Yes
	9.1.	Is there a discussion of findings?	Yes
	9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**		Yes
	10.1.	Were sources of funding and investigators' affiliations described?	Yes
	10.2.	Was the study free from apparent conflict of interest?	Yes